

ADDENDUM A

Amendments to 105 CMR 130.000 regarding medical control: **All language is new**

Add to 105 CMR 130.020,

Under definition of “essential health service” (excluded services list):

(I) Medical Control Service.

Under definition of “service:”

(BB) Medical Control Service means the organized provision of medical control as defined in 105 CMR 130.1501.

130.1500: Purpose

The purpose of 015 CMR 130.1500 through 130.1504 is to establish standards for those hospitals that provide medical control to licensed EFR and ambulance services.

130.1501: Definitions

The following definitions apply in 105 CMR 130.1500 through 130.1504:

Affiliate Hospital means a hospital that is licensed by the department to provide a medical control service and agrees to provide medical control to a licensed service pursuant to an affiliation agreement.

Affiliation Agreement means an agreement between the hospital and a service that meets the requirements of 105 CMR 170.300.

Authorization to Practice means approval granted to EMS personnel as defined in 105 CMR 170.020.

CMED means the medical communications subsystem within the statewide EMS communications system.

EFR Service means an EMS First Response Service designated as a service zone provider pursuant to a Department-approved service zone plan for the purpose of providing rapid response and EMS in accordance with 105 CMR 170.000.

Emergency Medical Services (EMS) means the pre-hospital assessment, treatment and other services utilized in responding to an emergency or provided during the emergency or inter-facility transport of patients to appropriate health care facilities.

EMS System means all the EMS providers and equipment; communications systems linking them to each other; training and education programs; the Regional EMS Councils and all of their operations; EMS plans, protocols, statutes, regulations, administrative requirements and guidelines; and all other components of such system, and their interaction with each other and with patients, providing equally for all patients quality care, operating under the leadership and direction of the Department.

Emergency Medical Technician (EMT) means a person certified by the Department to provide emergency medical services pursuant to 105 CMR 170.000.

Medical Control means the clinical oversight by a qualified physician to all components of the EMS system, including, without limitation, Statewide Treatment Protocols, medical direction, training of and authorization to practice for EMS personnel, quality assurance and continuous quality improvement.

Medical Direction means the authorization for treatment established in the Statewide Treatment Protocols provided by a qualified medical control physician to EMS personnel, whether on-line, via direct communication or telecommunication, or off-line, via standing orders.

On-line Medical Direction means the authorization for treatment established in the Statewide Treatment Protocols provided by a qualified medical control physician to EMS personnel via direct communication or telecommunication.

Qualified Medical Control Physician means a physician who meets the requirements of 105 CMR 130.1504.

Regional EMS Council means an entity created pursuant to M.G.L. c. 111C, §4 and designated by the Department to assist the Department in establishing, coordinating, maintaining and improving the EMS system in a region.

Service means a licensed ambulance service or EFR service as defined in 105 CMR 170.020.

Statewide Treatment Protocols means the Emergency Medical Services Pre-Hospital Treatment Protocols approved by the Department for application statewide.

130.1502: Standards for Hospitals that Provide a Medical Control Service

Each hospital that provides a medical control service shall:

- (A) Enter into an affiliation agreement that meets the requirements set forth in 105 CMR 170.300 with each service to which it provides medical control;

- (B) Make on-line medical direction available 24 hours a day, seven days a week to all services with which it has an affiliation agreement;
- (C) Designate an affiliate hospital medical director;
 - (1) The hospital shall ensure that the affiliate hospital medical director performs the duties specified in 105 CMR 130.1503.
 - (2) The hospital shall ensure that the affiliate hospital medical director meets the requirements set forth in 105 CMR 130.1504.
- (D) Provide data regarding medical control to the Department upon request;
- (E) Maintain operational communications equipment and participate in communications plan development, where appropriate, in compliance with the Massachusetts Emergency Medical Services Radio Communications Plan;
- (F) Ensure that all field communication of emergency on-line medical direction is recorded by CMED, at the hospital, or by other means;
- (G) Maintain and provide to the Department upon request a list of the physicians that provide on-line medical direction pursuant to the affiliation agreement and the requirements set forth in 105 CMR 130.1504;
- (H) Ensure that there is a process for skill maintenance and review available to EMS personnel employed by the service with which the hospital has an affiliation agreement;
- (I) Provide remedial training opportunities in the hospital emergency department and in operating rooms or skill laboratories, for remediation and education of all pertinent EMS skills and practices, including, but not limited to, advanced airway management;
- (J) Operate an effective quality assurance/quality improvement (QA/QI) program that includes, but is not limited to, regular review of trip records and other statistical data pertinent to the operation of the service with which the hospital has an affiliation agreement, in accordance with the hospital's QA/QI standards and protocols, in those cases in which ALS services were provided or in which ALS established direct patient contact;
- (K) Make available to the hospital's emergency department physicians and nurses and the EMS personnel employed by the service with which the hospital has an affiliation agreement, morbidity and mortality rounds and chart reviews at a frequency specified in the affiliation agreement;
- (L) Provide to the Department and the Regional Medical Director upon request a list of ambulance services with which it maintains affiliation agreements; and
- (M) Establish policies and procedures through which the service may obtain medications from the hospital's pharmacy.

130.1503: Duties of the Affiliate Hospital Medical Director

The Affiliate Hospital Medical Director shall:

- (A) Provide oversight to and ensure the clinical competency of the EMS personnel employed by the service with which the hospital has an affiliation agreement, including, but not limited to, the following:
 - (1) Authorization to practice;
 - (2) Remedial education to those EMS personnel found to be deficient in clinical practice; and

- (3) Notification to the Department within 48 hours of any instance in which he or she suspends, revokes, or restricts in any manner the authorization to practice of an affiliate EMS service's EMT or EFR. Such notice shall include the reasons for the suspension or revocation, and the affiliate hospital medical director's remediation plan for the EMT or EFR.
- (B) Ensure that all on-line medical direction is in conformance with the Statewide Treatment Protocols;
- (C) Provide appropriate orientation to all physicians who provide on-line medical direction pursuant to the affiliation agreement, including but not limited to information regarding local EMS providers and point-of-entry plans;
- (D) Coordinate the QA/QI program described in 105 CMR 130.1502(J) with the participation of the hospital's on-line medical direction physicians and the service medical director, if different from the affiliate hospital medical director;
- (E) Provide information requested by a Regional Medical Director to enable him or her to monitor the hospital's affiliation agreements; and
- (F) Maintain appropriate skills and knowledge through continuing education.

130.1504: Standards for the Affiliate Hospital Medical Director and Physicians Who Provide On-line Medical Direction

Each hospital that operates a medical control service shall ensure that each physician that provides on-line medical direction meets the following standards.

- (A) Current credentialing to practice as a physician in a Massachusetts hospital emergency department. Such credentialing shall, at a minimum, include demonstration of the following:
 - (1) Education for proper provision of on-line medical direction, as evidenced by
 - (a) Successful completion of an Emergency Medicine residency program, or
 - (b) Previous training and experience in medical direction.
 - (2) Proficiency in the clinical application of the current Statewide Treatment Protocols.
- (B) Proficiency in EMS radio communications.
- (C) In addition to the standards described in 105 CMR 130.1504 (A) and (B), the affiliate hospital medical director shall be board-certified in emergency medicine.

Companion changes to 105 CMR 170.000 (EMS regulation): New language is in **bold**;
deleted language is ~~stricken~~

170.300: Affiliation Agreements

Amend (A) as follows:

(A) To be licensed to provide ALS services, each ambulance or EFR service must have a current written contract with one hospital ~~with an emergency department staffed by physicians 24 hours each day~~ **licensed by the Department to provide medical control.** This agreement shall contain a reasonable and effective plan for medical control **and including include** the following features:

- (1) Treatment protocols and point-of-entry plans using regional guidelines that are in conformance with the Statewide Treatment Protocols, and other relevant regulations, policies and administrative requirements of the Department;
- (2) Designation of an affiliate hospital medical director, who shall have authority over the clinical and patient care aspects of the affiliated EMS service, including but not limited to the authorization to practice of its EMS personnel;
- (3) Provision of on-line medical direction in accordance with the Statewide Treatment Protocols 24 hours a day, seven days a week, by a hospital-based physician;
- (4) Operation of an effective quality assurance/quality improvement (QA/QI) program coordinated by the affiliate hospital medical director and with participation of on-line medical direction physician(s) and service medical director, if different from the affiliate hospital medical director, that includes, but is not limited to, regular review of trip records and other statistical data pertinent to the EMS service's operation, in accordance with **the hospital's QA/QI** standards and protocols, in those cases in which ALS services were provided **or in which ALS established direct patient contact**;
- (5) Operation of a program for skill maintenance and review for EMS personnel;
- (6) Ensuring EMS personnel have access to remediation, training and retraining, as necessary, under the oversight of the affiliate hospital medical director or his or her designee;
- (7) Regular consultation between medical and nursing staffs and **EMS personnel** ~~EMTs~~ providing ALS services, including but not limited to attendance at morbidity and mortality rounds and chart reviews;
- (8) A procedure by which a physician can maintain recorded direct verbal contact with the **EMS personnel** ~~EMT~~ regarding a particular patient's condition and order, when appropriate, the administration of a medication or treatment for that patient, to which such physician or his or her designee shall sign the trip record documenting the patient's care and transport by the **EMS personnel** ~~EMT~~; ~~and~~
- (9) Policies and procedures for obtaining medications from the hospital's pharmacy;

- (10) A procedure by which the service shall notify the affiliate hospital medical director of Department action against any EMT's or EFR's certification (denial, suspension, revocation or refusal to renew certification), or other Department disciplinary action (letter of reprimand, letter of clinical deficiency, advisory letter) against any EMS personnel employed by the service, and
- (11) If the service has more than one affiliation agreement, the identity of all hospitals with which the service has affiliation agreements and policies and procedures that set forth the duties and responsibilities of each affiliate hospital.

Amend (B) as follows:

(B) A service that has bases of operation in more than one EMS region shall maintain an affiliation agreement in each of the EMS regions in which it operates. A service that maintains more than one place of business within a single EMS region may maintain more than one affiliation agreement provided that it is in the public interest and the Department approves the additional agreement. No service that maintains a single place of business may enter into more than one affiliation agreement.

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170.795: Complaints

Amend opening paragraph as follows:

As interest requires, the Department shall investigate every complaint received, **including but not limited to reports received pursuant to 105 CMR 130.1503(A)(3) or 105 CMR 170.350**, about practices and acts which may violate M.G.L. c. 111C or any provision of 105 CMR 170.000.